

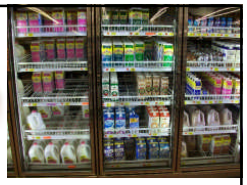

FSMA UPDATE INCLUDING SUPPLEMENTALS:

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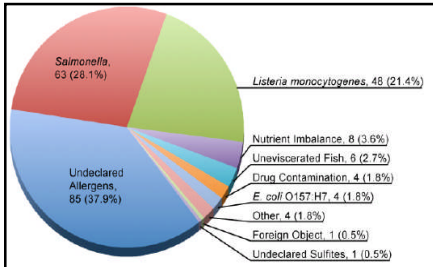
2014 CFSRS Webinar Schedule
(see www.cfsrs.com for current list, & dates):

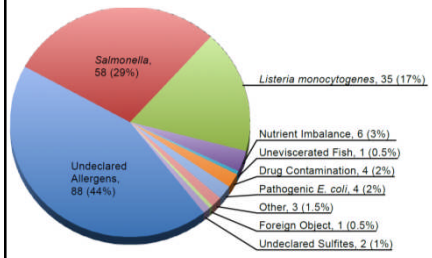
1. FSMA Preventive Controls, FSV, TPC & Intentional Contamination Update
2. Crisis Readiness: How to Prepare for Operational Failures, Large-Scale Disasters and Everything in Between
3. Food Defense Strategies & FSMA's Intentional Contamination Reg.
4. The Microbiology of Milk
5. Overview of Changes: 2013 Grade A Pasteurization Milk Ordinance
6. HTST & VAT Pasteurization Technology for Fluid Processors
7. Food Processing Instrumentation: Improving Control, Data Capture and Cost Management
8. Computerized Solutions for Food Processing Quality Assurance Programs
9. Industry Rights & Responsibilities During an FDA Investigation
10. SQF Practical Implementation Strategies
11. Survival Strategies on Managing a Recall

FDA Reportable Food Registry Statistics

Commodities	2010	2011	2012	2013
Bakery	16	20	18	22
Beverages	3	2	1	1
Dairy	18	16	20	10
Dressings/Sauces/Gravies	6	8	5	6
Egg	2	2	2	0
Frozen Foods	9	11	3	10
Fruit/Vegetable Products	12	9	5	3
Nuts/Nut Products/Seeds	16	16	13	15
Oil/Margarine	1	0	0	0
Produce - Fresh Cut	13	9	23	13
Produce – RAC	14	27	33	10
Seafood	17	18	17	19
Spices and Seasonings	17	25	8	12
Total	229	225	224	202



FY 2012 – Distribution of 224 Primary RFR Entries by Food Safety Hazard



FY 2013 - Distribution of 202 Primary RFR Entries by Food Safety Hazard

Infant Formula & Dietary Supplements Excluded from Reporting

Table 2. –The Effect of Activities on RACs That Are Foods	
Activities That Change a RAC into a Processed Food	Activities That Do Not Change the Status of a RAC
Canning	Application of pesticides (including by washing, waxing, fumigation, or packing)
Chopping	Coloring
Cooking	Drying for the purpose of storage or transportation
Cutting	Hydro-cooling
Drying that creates a distinct commodity	Otherwise treating fruits in their unpeeled natural form
Freezing	Packing
Grinding	Refrigeration
Homogenization	Removal of leaves, stems, and husks
Irradiation	Shelling of nuts
Milling	Washing
Pasteurization	Waxing
Peeling	Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant
Slaughtering animals for food and activities done to carcasses post-slaughter, including skinning, eviscerating, and quartering	
Slicing	
Activities that alter the general state of the commodity	

Plant Registration

- Failure to register could result in FDA declaring facility is “suspended.
- Secretary of Health & Human Services only person authorized to suspect facility’s registration
- FDA will conduct informal hearing and make determination
- Facility has 2 business days to appeal suspension in writing to FDA
- If FDA suspension notice upheld, facility cannot manufacture, process, package, receive or store food/feed and faces possibility of FDA detaining or seizing food/feed
- Registration fee ???

CFSRS Improving Food Safety, One Plant at a Time

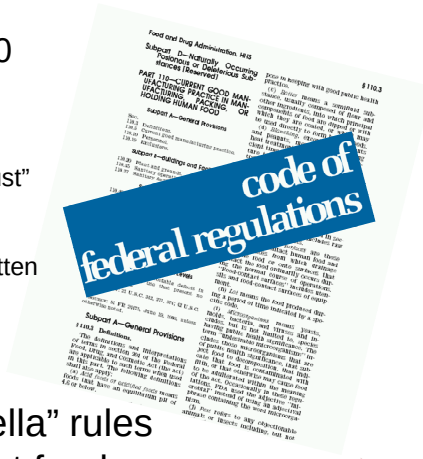
Seven (7) Foundation FSMA Rules

1. **Human Food preventive controls**
2. **Animal Feed preventative controls**
3. **Produce rules – will set standards for farm growing practices**
4. **Foreign Supplier Verification Proposed Rule – importer accountability program to ensure imported foods are produced under the same standards/level of protection, as our new preventative control of produce standards.**
5. **Accredited Third Party Certification of Foreign Suppliers.**
6. **Safe Food Transport rules**
7. **Intentional Adulteration provision**

CFSRS Improving Food Safety, One Plant at a Time

21 CFR 117 to replace 21 CFR 110 in approximately 3 years

- “Shall” replaced with “Must”
- “Should” removed or use minimized.
- FDA plans to provide written guidance on all “should” items in 117.



They are “umbrella” rules to help prevent food safety defects

CFSRS Improving Food Safety, One Plant at a Time

New food GMP Terms (pages 256 – 257)

Qualified individual

- Person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.
- Must directly supervise or prepare the plant's food safety plan

Food Safety Preventive Controls Alliance (FSPCA)

The alliance will:

- develop standardized hazard analysis and preventive controls training and distance education modules for industry & reg. personnel;
- design and deliver a state-of-the-art distance learning training portal at the IIT IFSH Moffett Campus in Bedford Park, Ill.;
- develop "train-the-trainer" materials
- create a technical assistance network for small- and medium-sized food companies;
- develop commodity/industry sector-specific guidelines for preventive controls;
- assess knowledge gaps and research needs for further enhancement of preventive control measures; and
- identify and prioritize the need for and compile critical limits for widely used preventive controls.

New food GMP Terms (pages 256 – 257)

Preventive Controls

Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

FSMA Required **"Preventive Controls"** Processing Equipment Impacts

1. **Supplier Management**
2. **Allergen Control Program**
3. **Process Controls**
4. **GMP Program as defined in 21 CFR 110 (117)**
5. **Product Traceability**
6. **Recall Plan**
7. **Intentional Contamination – Food Defense**

All Preventive Controls listed above must be monitored, verified and have corrective action documentation.

FSMA Required **"Preventive Controls"**

8. Employee Training (GMPs, HACCP, sanitation, allergens, environmental monitoring, food defense, food regulations, chemical use)
9. Validation of
   a. Processing Equipment Cleaningent Cleaning & Sanitizing
   b. Pathogen Reduction Method
10. Processing & Laboratory Equipment Calibration
11. Review of Records

All Preventive Controls listed above must be monitored, verified and have corrective action documentation.

Major Provisions of Proposed Rule HACCP-Like Provisions

- **Written Food Safety Plan**
- **Hazard Analysis**
- **Preventative Controls for Hazards Reasonably Likely to Occur**
- **Monitoring Records to Prove Controls Effective**
- **Corrective Actions**
- **Verification**
- **Validate Controls**
- **Other Records**

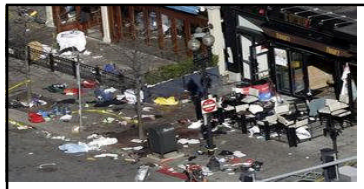
National Conference on Interstate Milk Shipments — GAPS Between FSMA's Preventive Controls & the Grade "A" PMO

1. Written Food Safety Plan
2. Hazard Analysis
3. Preventive Controls Addressing Hazards Reasonably Likely to Occur
4. Monitoring
5. Corrective Actions
6. Verification
7. Supporting Records
8. Process Controls
9. Food Allergen Controls
10. Sanitation Controls
11. Recall Plan
12. Radiological Hazards
13. Transportation Practices
14. Equipment PM Program

Records Protected under FSMA

- Records from farms
- Records from restaurants
- Recipes, as defined in 21 CFR 1.328 - A "recipe" is the formula, including ingredients, quantities, and instructions necessary to manufacture a food. Because a recipe must have all three elements, a list of the ingredients used to manufacture a food, without quantity information and manufacturing instructions, is not a recipe.
- Financial data
- Pricing data
- Personnel data
- Research data
- Sales data other than shipment data regarding sales

What about equipment records?



FSMA Food Defense/Intentional Contamination Requirements

- **Food Defense –** FDA working with the Department of Homeland Security and USDA to perform food vulnerability assessments and publish regulations to prevent the intentional adulteration of food products.
- **Intentionally Introduced Hazards - deferred**
- **FDA website on food defense:** Good tools to evaluate your vulnerability and develop multi-layered program for food defense that relies on:
  - physical barriers (fences, locked doors & windows, etc.)
  - procedures (sign-in, visitor picture ID requirements, etc.)
  - employee training-reporting suspicious activity
- Challenge once per year

Expected FDA FSMA Safe Transport of Food Requirements

1. **Temperature control**
2. **Sanitation**
3. **Loading & Unloading**
4. **Segregation & Prior Cargo**
5. **Training of transport staff**
6. **Recordkeeping**

FDA published the Safe Food Transport Regulations on January 31, 2014 – Comment Period May 31, 2014

FDA's "Supplementals" Timeline

Current GMPs & Preventive Controls for Human Food	Comment Period Closure 12/15/14 Final Publication By 8/30/15	Main Points (HA – Hazard Analysis; PC – Preventive Controls)
		1. Farms exempt from HA & PC development even if they pack & dry RAC for others. 2. Change criteria for HA & PC from "reasonably likely to occur" to "significant hazard" based on severity & probability (see Table 6 for examples-p70). 3. Written procedure for finished product testing. 4. Written procedures for environmental monitoring. 5. Written procedures for supplier control program 6. Include intentionally introduced economic hazards in HA

Supplementals: Preventive Controls Overview:

1. Hazard Analysis: Reasonably Likely To Occur (RLTO) has been replaced with "significant hazard"
   - Significant Hazard: A "known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of the hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls . . . as appropriate to the food, the facility, and the nature of the control."
   - SMOP: Significantly Minimize Or Prevent
   - Facilities would evaluate identified hazards by assessing "the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventative controls."
   - Must consider economically-motivated adulteration

Supplementals: Preventive Controls Overview:

2. Management of Controls (Level of Oversight)
   - FDA agrees that not all controls should be managed the same way ("Sliding scale" concept)
   - Repeated use of the phrase "as appropriate to the nature of the preventive control"
   - Preventive controls would be implemented to SMOP significant hazards
   - The regulations would explicitly provide that:
     - Preventive controls include controls other than those at critical control points (CCPs)
     - There may not be controls at CCPs
     - Parameters (limits) only needed for process controls
   - Level of oversight for the various preventive controls is flexible based on the nature of the control/ Examples:
     - Not all monitoring activities generate records
     - Not all corrections require records
     - Not all preventive controls require validation
     - Not all corrective actions require verification

Supplementals: Preventive Controls Overview:

3. Product Testing:
   - "Product testing" would encompass ingredient testing, in-process testing, and finished product testing
   - Product testing procedures would be required to specify the procedures for identifying samples and the procedures for sampling, the test conducted, corrective actions, etc.
   - FDA suggested RTE products appropriate candidates for product testing
   - FDA proposes to require product testing as a verification activity ("as appropriate")
   - FDA is also reopening the comment period for the agency's previous request for comment on how and when product testing programs are appropriate

Supplementals: Preventive Controls Overview:

4. Environmental testing (no Zone 1 requirement)
   - As part of the hazard evaluation, FDA proposes to require an evaluation of environmental pathogens whenever a RTE food is exposed to the environment prior to packaging and the food does not receive treatment
   - Environmental monitoring will be a verification activity if contamination of a RTE food with an environmental pathogen is a significant hazard
   - Environmental monitoring procedures would need to:
     - Identify the locations and sites for routine environmental monitoring;
     - The timing and frequency of monitoring; and
     - Address the presence of an environmental pathogen or appropriate indicate organism detected through environmental monitoring
   - Facility corrective action procedures would be required to address the presence of an environmental pathogen or appropriate indicator organism in a RTE product tested through product testing
   - Comment period is reopened on when and how environmental monitoring programs are appropriate

Supplementals: Preventive Controls Overview:

5. Supplier Verification
   - "Suppliers" are establishments that manufacture or process food, raise animals, or harvest food that is provided to a receiving facility without further processing
   - Supplier program required for raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt.
     - Facilities that pack or hold food without manufacturing are *not* "suppliers"
     - Facilities would not be required to establish a supplier program for food they only pack or distribute (they would not be a "receiving facility")

Supplementals: Preventive Controls Overview:

5. Supplier Verification (cont.)
   - If you or your customer control the hazards, no SP required
   - Limited to circumstances where the supplier is controlling any significant hazards
   - Supplier risks taken into account – Hybrid approach for onsite audits
   - "Receiving facilities" manufacture or process raw materials or ingredients that they receive from suppliers
   - Receiving facilities would be required to establish supplier verification activities if they receive material from a distribution center and they identify a significant hazard in the material that is controlled by the supplier to the distribution facility

Supplementals: Preventive Controls Overview:

5. Supplier Verification (cont.)
   - If a facility receives an ingredient from a supplier, but the hazard is controlled by the supplier's supplier, the receiving facility would conduct supplier verification activities that would include verifying that the supplier has conducted appropriate verification that its supplier has controlled the hazard. For example, the receiving facility could review the supplier's food safety records for its supplier program
   - FDA is seeking comment on how supplier verification activities should address gaps in the system where:
     – Materials pass through more than one facility that would not be required to verify control of hazards; and
     – Raw agricultural commodities such as fresh produce will not be handled by any facilities that would be required to have preventive controls before reaching consumers

Supplementals: Preventive Controls Overview:

5. Supplier Verification (cont.)
   - Require verification activities, as well as documentation, to ensure materials are received only from approved suppliers
     – No "list" required
     – When necessary and appropriate, materials could be received on a temporary basis from unapproved suppliers subject to adequate verification activities before acceptance for use
   - Minimum Records for Supplier Verification:
     – Documentation of an supplier audit
     – Records of sampling and testing;
     – Records documenting review of supplier's relevant food safety records; and
     – Documentation of alternative verification activities for suppliers that are qualified facilities or farms not subject to the produce rule
   - FDA explains that it would expect many of the records to be accessible during facility inspections because they would be in electronic form

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Supplementals: Preventive Controls Overview:

5. Human Food By-Products Diverted to Animal Feed
   - Subject to human food requirements up to point of diversion, then utilize the animal food GMPs for holding and distribution
6. Significant change in very small business definition to $1 million total annual sales of human food
7. Moderated the criteria for FDA to revoke status of "qualified facilities"
8. Revised definitions for "farms," "packing," and "holding"

FDA's "Supplementals" Timeline

Current GMPs & Preventive Controls for Animal Food	**Comment Period Closure** 12/15/14 **Final Publication** By 8/30/15	**Main Points (HA – Hazard Analysis; PC – Preventive Controls)** 1. Human food processors already complying with human food requirements & cGMPs would not have to implement additional PCs or GMPs related to supplying animal foods as a byproduct (part 507 including HA & PC not required). 2. Change criteria for HA & PC from "reasonably likely to occur" to "significant hazard" based on severity & probability (see Table 6 for examples-p70). 3. Written procedure for finished product testing. 4. Written procedures for environmental monitoring. 5. Written procedures for supplier control program 6. Include intentionally introduced economic hazards in HA

FSMA GMPS for Animal Feed October 29, 2013 Fed Register Notice:

- Proposed Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals – comment period closes February 26, 2014
- Draft Quantitative Risk Assessment of risk of Activity/Animal Food combinations for Activities (Outside Farm Definition) Conducted in a Facility Co-Located on a Farm – no comment period, informational
- Proposed Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Public Meeting on Proposed Rule – comment period close; Notification of public meeting; request for comments
  - Nov. 21, 2013: College Park, MD
  - Dec. 6, 2013: Sacramento, CA

Supplementals: Animal Feed Preventive Controls Overview:

1. Animal Food GMPs – Revised to be more tailored to diverse animal food facilities
2. Revised definition of Very Small Business to $2.5 million total annual sales of animal food

Economic Adulteration

- FDA proposes to require the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain
  - Focus is on adulterants that are reasonably likely to cause illness or injury in the absence of their control
  - Not focused on adulterants that solely affect quality and value
- FDA suggests it is practicable to determine whether EMA is reasonably foreseeable by focusing on circumstances where there has been a pattern of adulteration in the past

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Summary of FSMA Changes

- Requires a Food Safety Plan
  - Preventive controls and Recall Plan
  - Defined Records to determine compliance
- Expands FDA's Routine Inspectional Records Access
  - Food Safety Plan, Hazard Analysis, Preventive Controls, Monitoring S Corrective Action SOPs, Verification SOPs, Recall Plan, and all associated records
- Expands FDA's Non-Routine Authority
  - Expanded from authority provided by the Bioterrorism Act of 2002
  - In a SAHCODHA event (serious adverse health consequences or death to humans or animals), FDA has expanded access to records and has legal access to view and copy records
  - Need "reasonable probability"
- Potential future inclusions in final rule
  - Environmental and finished product testing
  - Customer/consumer complaints related to food safety
  - Monitoring of supply chain (supplier verification)
  - Traceability

FDA FOOD SAFETY MODERNIZATION ACT

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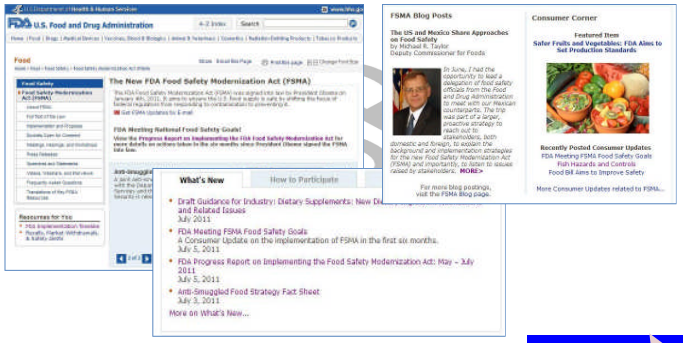
Snapshot of FSMA homepage elements at: http://www.fda.gov/fsma



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Thank You!

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Who Has the First Question ?

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